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**Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/088,951	06/02/98	CHEEVER	M 920010.535

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HM12/0824

EXAMINER

UNGAR, S

ART UNIT	PAPER NUMBER
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1642

14

DATE MAILED: 08/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/088,951

Applicant(s)

Cheever et al

Examiner

Ungar

Group Art Unit

1642



☒ Responsive to communication(s) filed on Jun 8, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1, 7-9, 11, and 12 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1, 7-9, 11, and 12 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. The Amendment filed June 8, 2000 (Paper No. 12) in response to the Office Action of March 6, 2000 (Paper No. 11) is acknowledged and has been entered. The Declaration filed June, 29, 2000 (Paper No. 13) is acknowledged and has been entered. Previously pending claims 2 and 6-10 have been canceled and claims 1, 7, 8 and 11-12 have been amended. Claims 1, 7-9 and 11-12 are currently being examined.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The following rejections are being maintained:

***Claim Rejections - 35 USC § 112***

4. Claims 1, 7-9 and 11-12 remain rejected under 35 USC 112, first paragraph, for the reasons previously set forth in Paper No. 11, Section 5, pages 3-5.

Applicant argues that removal of the terms "foreign" and "homologous" overcomes the rejection. The argument has been considered but has not been found persuasive because Applicant has not addressed the issues raised to (a) how to make the immunogen so that it will function as claimed (b) how to use an immunogen with at least 50% sequence identity to the self tumor. The deletion of the terms "foreign" and "homologous" does not obviate the rejection since the newly amended claims are drawn to amino acid sequences found in a non-human source (that is from sources that are foreign to a human) that are "not identical" to the human sequence, which clearly reads on homologues. Applicant's arguments have not been found persuasive and the rejection is maintained.

***Claim Rejections - 35 USC § 102***

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5. Claims 1, 7-9 and 11-12 remain rejected under 35 USC 102(e) for the reasons previously set forth in Paper No. 11, Section 5, pages 3-5.

Applicant argues that claim 1 is now drawn to a method of eliciting or enhancing an immune response to a human self tumor antigen comprising immunizing a human being with a human self tumor antigen, which is found in a non human source, the amino acid sequence of which is not identical to the human antigen and that US Patent No. 5,925,362 does not teach or suggest the methods of the newly amended claims. The argument has been considered but has not been found persuasive because US Patent No. 5,925,362 teaches as disclosed previously and specifically teaches, as previously disclosed, that the immunogen is a fusion protein which is not identical in amino acid sequence to the human tumor antigen and that because of its recombinant production, its source is a non-human source, that is *E Coli*, yeast or fungi (col 5, lines 31-33). Applicant's arguments have not been found persuasive and the rejection is maintained.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

6. Claims 1, 7-8 and 11-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7-8 and 11-12 are indefinite because Claim 1 recites the phrase "immunizing a human being with **the** (emphasis added) self tumor antigen or a portion thereof with an amino acid sequence as found in a non-human source, wherein the non-human antigen or portion thereof is not identical in amino acid

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sequence to the human antigen". The claims are confusing because it is not clear how one can be immunized with "the" self-tumor antigen which is a human self tumor antigen when the antigen comes from a non-human source and its amino acid sequence is different than that of the human tumor antigen.

Claim 11 is indefinite because it is not clear at which step the pharmaceutically acceptable carrier or diluent is "included". The rejection can be obviated by amending Claim 1 to read, for example, "immunizing a human being with a composition comprising the self tumor antigen....." and amending claim 11 to read, for example "The method of claims 1, 7, 8,9 wherein the composition further comprises a pharmaceutically acceptor carrier or diluent".

7. All other objections and rejections recited in Paper No. 11 are withdrawn.
8. No claims allowed.
9. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

**A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT**

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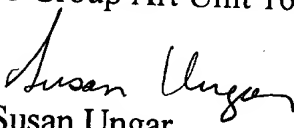
TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.

  
Susan Ungar  
Primary Patent Examiner  
August 22, 2000